

Policy gap: regulation versus promotion of technology

Paper provided for the 6th Globelics Conference, 2008, Mexico

Ebrahim Souzanchi Kashani

PhD Student of Science and Technology Policy Studies,
SPRU¹, University of Sussex, Brighton, U.K.

Email: es87@sussex.ac.uk

Abstract:

Based on analyzing two different areas of research about regulation of technologies, which are the literature of innovation and regulation on the one hand, and risk and governance on the other hand; the present study suggests that there are some conceptual gaps in the policy literature. Using the case of GM foods regulation in the context of European Union, it will show some limitations of both streams. As a initial proposed framework for policy analysis as well as policy making, it shall suggest a new conceptual model that is supposed to be richer than the previous versions.

¹ I must be so thankful for what I have learned from Prof. Erik Millstone during my staying at SPRU this topic and also his kind recommendations on this paper.

Introduction:

The field of innovation studies as a multi and somehow an interdisciplinary area², mostly has tried to understand “how innovations occur” (Fagerberg 2005). After the Second World War, and in light of some questions mainly in studies relating to the growth issue, some scholars began to investigate the mechanisms behind the new technological changes (Martin and Nightingale 2000). The problems of the production function (Solow 1956, 1957) in explaining the forces behind technical change (Abramovitz 1956) raised the central question of the field to investigate the inside of what has been called the black box (Rosenberg 1963, 1982).

This stream of research, however, always has had some elements of government intervention for its potential role in promoting the conditions for innovation. From the Bush's (1945) report on the main role of government in supporting basic research for the sake of economic growth, health and security to famous papers of Nelson (1959) and Arrow (1962) which have suggested the government intervention in science production because of the market failure until the current evolutionary (Nelson and Winter 1982) and systemic (Freeman 1987, Lundvall 1988, 1992, Nelson 1993) understandings of innovation and technological progress emphasizing on the role of governments in institutional setups and capability building; all scholars were trying to find out how governments could take an active role in promoting innovation and learning, than a passive laissez faire version of letting market to do what it can as the best mechanism of economic administration.

Regulation of technologies as social constructs, especially new and emerging technologies, is among the different functions, which has been suggested for government's interventions. In the words of Rothwell (1992), it traced back initially to the increasing public awareness of the negative impacts of unrestrained industrialization in the mid-1960s such as health and safety problems in the workplaces and degradation of the physical environment (p. 447). Although the energy crisis of 1973-1974 led to the new deregulation for improving industrial innovation; widespread concerns about different externalities of technological progress renewed pressures for tighter control through more stringent government regulations (p. 448).

As a result, in this field of inquiry scholars began to explore the impacts of regulation on innovation (Allen et al. 1978) considering regulation as an environmental factor that must be overcome by firms, and somehow modeling the dynamics of interaction between regulation and innovation helping to explore the conditions under which the firm would be more likely to innovate (e.g. Montalvo 2007) and finding the ways in

² Both of multi and inter disciplinary approaches are investigating a topic. The difference is that in the former “there exist many disciplines... each of which has a particular way or several ways of examining the topic”; while the latter “holds that characteristics of the subject matter require a method that is unique to that topic” (Bowden 1995 p. 68). In the other words, in understanding a topic, firstly different disciplines come in to investigate it based on their methodologies and after some learning among them, they begin to develop some unified and integrated approaches which is called interdisciplinary.

which regulations pose minimal barriers for innovations presumes that the ways of regulations is important in shaping innovations, rather than their existence per se (Rothwell 1992 p. 448). Plausibly, these studies are concerning about the benefits of new technological progresses, rather than their potential risks and disbenefits, or possible harms.

On the other side, there are vast and widespread studies concerning the regulation of and management of risks, especially arising from new technological advances in some fields such as GM foods (e.g. look at the 2nd issue of the Journal of Risk Research in 2000), Nano technologies and so on. Different scholars based on different philosophical assumptions have worked on the ways governments can regulate new technologies considering their risks and possible harm effects as the major issue that must be tackled by governments.

Hence; while Rothwell has defined regulation as “the control of particular situation for the benefit of society” and “stimulation of technological innovation”(p. 451), Jasanoff (1995) introduces a new view to the regulation as “a kind of contract that specifies the terms under which state and society agree to accept the costs, risks and benefits of a given technological enterprise”(p. 311). Apparently, two major differences between these views must be taken into account which are 1) emphasizing on the costs and risks of technologies in addition of their benefits and 2) the importance of a kind of democratization of regulation in which it is not a mere control by government, but a participatory method in which society plays its role and therefore must accept the terms of its resulted contract. In this situation “most hazardous technologies confer substantial benefits on society in the form of better health, increased productivity, and in general a higher quality of life” (Jasanoff 1986 p. v).

The present paper argues that there is a gap in the literature to encompass the new developments in the regulation of technologies mostly in the new high tech fields such as biotechnology. It will argue that considering the new developments in the studies concerning risks and sustainable development would yield a new and richer understanding of the regulatory environment of technologies.

It will argue that one of the main assumptions in the innovation studies is not true for the case of GM foods regulation and changing this assumption will lead to changing the whole policy making approach, and therefore a need for new analytical tools. This assumption which briefly described before is taking for granted the importance of innovation and trying to find the ways in which regulation pose minimal barriers for innovation.

It will accept the case of regulating GM foods as an example in which the real problem is not concealing the regulation for the sake of promoting innovation, but wider and broader issues in a democratic process of regulation. The new forms of regulation in the E.U. such as precautionary approach might be seen as the consequence of paying more attentions to risks than benefits of technologies, or at least being aware of the high uncertainties around those technologies.

Conceptually, there is no analytical tool in the hands of governments and policy makers for making balances and deciding about new technologies consisting both risks and benefits simultaneously. The current monograph hopes to contribute in this respect using the models developed for regulation in the situation of risks and modify them to can consider the framing assumptions of both risks and benefits and therefore pave the way for sounder policy decisions in a more explicit manner.

In the following sections, the paper tries to highlight this policy gap by illustrating the literature of regulation from innovation studies in the next part and then the risk regulations in the third section. The fourth section tries to identify the characteristics of both strands and the limitations of each of them to can provide an analytical policy tool for government's regulatory decisions. This part suggests a new conceptual framework for decision making based on the capabilities of both trends, which can be used also as an analytical tool for policy analysis.

Innovation studies of regulation:

In this part, first of all some general theoretical insights in the field of innovation studies shall be presented which are seen as rationales for policy interventions. Then, it shall illustrate the studies concerning regulation, as a part of innovation policies, which mostly have been done by scholars in the field of innovation studies. As it will be discussed in this section, one of the most important assumptions behind those studies is accepting the importance of innovation as a determining factor for the progress of a society and finding the ways that regulations do not make major barriers for the innovation processes. In the selection of the below works, I shall try to discuss works of some famous scholars as the leaders of the innovation studies filed.

STI Policy Rationales:

Overall it is possible to count 7 rationales for the government intervention in the science, technology and innovation area. The changing rationale of STI policy could be traced in moving from neo-classical school to the evolutionary theory of economics (Borras and Lundvall 1997). The neo-classical approach based on the market failure (Nelson 1959 and Arrow 1962) prescribes the intervention of government just when the market mechanism fails to operate properly.

For science, an argument is that the costless transformation characteristic of science would prevent firms to appropriate the full benefits of their R&D. Subsequently, they under-invest in its production (Arrow 1962). In terms of technology, its intrinsic uncertainty restrains obtaining the Pareto optimal point (Metcalfe 1994, 1995). In both situations, there is a need for government intervention. Moreover, the capability of government to handle the situation is another illustrated point (Edquist 2001 p.220): "Two conditions must be fulfilled for there to be reasons for public intervention in a market economy:

1. The market mechanism and capitalist actors must fail to achieve the objectives formulated; a *problem* must exist

2. The state (national, regional, local) and its public agencies must also have the *ability* to solve or mitigate the problem”.

The rival of this simple justification of policy is the complicated Neo-Schumpeterian rationales for STI policy. Based on the evolutionary theory of economic growth (Nelson and Winter 1982) and the systemic approach to the innovation including institutions (e.g. Freeman 1987, Lundvall 1988) there are very complicated discussions about STI policy rationales. I have summarized the rationales in three categories that in spite of their overlaps; it seems they are insightful. The first category includes rationales stemmed from innovation system approach. Second category refers to the rationales which come from evolutionary economics and the last one is the result of other innovation studies.

Innovation system rationales could be divided into arguments that either point out to the importance of institutions or the systemic role of actors. The former argues that while markets play a very important role in innovation, they exist in the context of social institutions that might be more fruitful targets of policy intervention (Lundvall 1992). Different studies show that many non economic factors, such as social, might be dominant in shaping the innovation (Hughes 1987). The latter claims that firms are not innovating in isolation, instead they are interacting with different actors and their systemic relationships defines the success of innovation (Edquist 2005)

The evolutionary theory also has some implications for STI policy. It means that the steady state equilibrium does not exist through continues change of the economy (Edquist 2001). “A distinctive feature of the evolutionary approach is its adoption of a behavioral theory of the firm and its focus upon learning processes and adaptive behavior” (Metcalf 1994). While the principle of evolutionary theory is twofold: variety and selection; the aim of technology policy is also twofold: to stimulate the generation of variety and to prevent the dominance of one technology due to the selection mechanism (Smith 1991). Accepting the importance of firms’ behavior, technology policy is defined: “as policies that are intended to influence the decisions of firms to develop, commercialize or adopt new technologies” (Mowery 1995).

The innovation studies, as the source of the last category, have highlighted some aspects of innovation, chief among them are the uncertain nature of innovative activities (e.g. Nelson and Winter 1977), the cumulative and path dependency characteristics of technical knowledge (e.g. Nelson and Winter 1982 on technological trajectories or Dosi 1982 on technological paradigms) and the importance of scientific knowledge in the innovation of firms (e.g. Dosi 1988).

The summary of these rationales are as follows:

1. There are many institutions in shaping the innovation, rather than market that might be very important in policy making. Their role and importance could be different in relation to the science, technology and innovation.
2. Innovation is a systemic phenomenon that many actors are playing in it. Similar to the innovation that its success depends on a coordinated system of actors,

scientific and technological achievements are also be determined by a good arranged system.

3. Firms are the most important actors in the innovation process that their learning behavior is a target of policy. While technology and innovation take the high values to firms, science might hesitate to do the same.
4. The selection mechanism may lead to domination of one form of technology. The role of policy could be breaking the paradigm through providing some new opportunities. This situation due to the differences between science and technology is highly related to the technology, not the science.
5. Innovation and technology are highly uncertain and diverse. A role of government could be reducing these uncertainties through some policy tools. These uncertainties means that many technological developments need time to change the reality, to find the value of their conjectures; nevertheless, science does not need this time, because its reality is available.
6. The cumulative and path dependent learning is the main driver of many innovations. Government should be care about this issue either to prevent the cumulateness of technological knowledge in particular firms; or to promote the monopoly in the market to increase its international competitiveness. In terms of science, there is a general agreement for the need of distributing knowledge not only in the universities; but also throughout the society (the issue of public understanding of science).
7. Scientific knowledge is very important in many innovations that lead to considering the role of science in innovation. As a result, government should consider the relationships between science and technology and facilitate the needed interactions between them.

Based on these insights, different scholars discussed the role and impacts of regulation on innovation which will be presented below. The discussion of these studies shows that they are mostly based on one important assumption which is the eminent importance of innovation as a priority for the policy making, especially in the advanced countries. In this framework, regulation is one of the government tools in promoting innovation for the sake of increasing the rate of growth, or other similar aims.

Studies of regulation:

Utterback with some of his colleagues in 1978 ran a research study investigating the impacts of regulation on innovation in five different industries between five different countries (Allen et al 1978). Their study presupposed regulation would affect the firm's environment, which is a determining factor in their innovation performance. The result of their research showed no indication of the impacts of government's intervention on success or failure of those innovation projects. They concluded that technologically innovative firms have been relatively successful in coping with government regulation.

Though this study was empirical in nature; however it tried to shed more light on the effects of regulation on innovation emphasizing on the ways firms react in response to the different regulatory signals. Consequently, they did not try to provide new understandings about the good versus bad, or constructive versus non- constructive

modes of regulations; instead the regulatory framework has been taken for granted as a situational condition, or a constant that would affect the innovative behavior of firms. However, it might be clear that the major concern of this study is to find the impacts of regulation on innovation as the core of economic activities emphasizing on the firms as the central actor of that game, and finally concluded that technology has been successful in coping with regulation.

The effect of 1962 Kefauver-Harris amendments to the Food, Drug and Cosmetic Act on the firms research and development strategies and behaviors has been discussed by Schnee (1979) to highlight the adverse effects of this regulation on innovation. The amendment “had two major objectives: (1): closer control over the premarket testing of new drugs, and (2) alteration of the criteria for the approval to market new drugs” (p. 366). The paper discussed how this amendment increased the costs of R&D, lowered the innovative outputs of firms as the principal dysfunctional consequence of the 1962 legislation, and changed the activities from research to the development and finally eroding the world wide technological leadership of the U.S. firms. Like the previous study, also this work did not suggest any policy improvements for helping the firms’ innovative behaviors; though it is clear that the paper sounds its support showing the new R&D problems of firms stemmed from the new regulation.

In a study of innovation among firms in the food sector, Ettlie (1983) found that the government intervention in the sector tends to discourage innovation and therefore there is a need for some policy improvements. He suggested seven national science and technology policy recommendations for changing the role of government from a discourager to encourager of innovation in that sector. The general framework that he used is similar to Utterback conceived context influences the form and long range plans of organizations that in turn will affect its capability and inclination to innovate. It is plausible to realize that this study tried to found the regulatory effects on the innovation behavior of firms and the possible ways of changing the regulatory framework to can promote innovation.

Patel and Pavitt (1987) compared the policy challenges of Japan, USA and W. Europe in increasing the technological levels concluding that the main policy challenges of W. Europe are to increase the rate of growth of innovative activities in lagging countries. Among particular policy problems of W. Europe, the effects of social legislation on worker flexibility and mobility, the problem of national regulations on intra-European competition are worth noting. While this study did not consider the effect of national policies as a contextual factor on the firms’ activities; however it taken for granted the high value and importance of innovation and the ways that policy must help to increase the rate of growth through innovative processes.

Although at the end of paper they admitted that any “policy implications of technology should be based on a fully worked out theory”, but because “there exists no satisfactory theory”, they assumed “that it is welfare inefficient for an OECD country or region to be behind the world technological frontier” (p. 78) as the basis for their policy recommendations. This assumption emphasizes on the importance of technological improvements, or progress, as the basis for policy makings in, at least, OECD countries.

Therefore, the real policy problem would be how it is possible to increase, or enhance the innovative performance to can reach the world class technological capabilities.

While the high rate of regulations in the mid-1960s decreased after the energy crisis of 1973-1974, new concerns about pollution, global warming and other issues caused increasing the government interventions in regulating technologies. Rothwell (1992) discussed the lessons from past experiences of the negative impacts of regulations on firms to can suggest how is it possible to minimize the negative effects of environmental regulations; while at the same time offering adequate protection to the environment. In his discussion, Rothwell concluded “it was often not regulation *per se* which caused the greatest problems, but rather the way in which specific regulations were formulated and implemented, for example:

- Unrealistic regulations;
- Lack of clarity and precision in regulations;
- Lack of a proper scientific basis for regulations;
- ... (p. 455).

From the aim of his study, which is minimizing the negative impacts of environmental regulations, and its definition of regulation as: “the control of a particular situation for the benefit of society” and “stimulation of technological innovation” (p. 451), it is obvious that his major concern is the importance of innovation in regulations as the major determinant factor; an assumption nearly close to the previous mentioned works.

Other studies in the later time also chose a similar approach to regulation. Thomas (1994) based on the organizational economics theory of the firm, explained how the regulatory framework of the U.K. led the British firms into international competitiveness; while the French system persuaded its firms to focus on a protected local market away from worldwide industry. Lanjouw and Mody (1996) described the effects of environmental regulatory acts over the 1970s and 1980s on the direction of innovations and environmental patents. They argued on the positive effects of this regulation on changing the motivations for innovations concerning abating pollutions, which served as focusing devices for motivating innovations.

Bourreau and Dogan (2001) analyzed the relationships between regulation and innovation in the telecommunications industry to find out which regulatory systems are likely to promote innovation in a fast-growing telecommunications industry. Similarly and in a more comprehensive study, Buhrlen et al (2003) analyzed the impacts of regulation on the innovation in the E.U. pharmaceutical sector. Based on a behavioral approach, Montalvo (2007) tried to present a dynamic model of interaction between regulators and firms, which seems to be able in exploring the conditions under which firm would be more likely to innovate.

To sum up, the above inspection of the literature concerning regulation shows that many commentators saw innovation at a core activity, while regulation and its other related factors in an ancillary role. Thereby, their major concerns would be how is it

possible to regulate technologies in a way that has the minimal effects on the innovative outputs of economy. The next section, which wants to illustrate the case of GM policy making, especially in the context of Europe, aims to show that this assumption is not accurate in some real policy situations and therefore the suggested models and approaches are not able to analyze and explain those policy situations. As a result, there is a need for richer models to can consist more factors relating risks and uncertainties as well as increased democratic methods of regulation.

Risk and policy making:

In this section, I shall try to illustrate the new developments in policy and regulation facing risks and uncertainties, which are mainly the products of 1990s renewed concerns about risk and risk society. Below I shall present the conceptual developments of the models in the field following by real policy problems in the case of GM foods, particularly at the E.U. Those developments are come from studying the role of science in policy making, particularly when science is obliged to provide the reliable information about the risks of new technologies.

Conceptual developments:

It is largely believed that in the late twentieth century, industrial societies are confronting risk and uncertainty as a dominant issue. Jasanoff (1986) has noted that: “avoiding risk is a central preoccupation of our age. We are haunted daily by risks of varying probability, magnitude, and emotive impact: dioxin in the air, thrihalomethanes in the drinking water, pesticides on our food, drunken drivers on the highways...” (p. 1).

These concerns, among other factors, provide a circumstance for scientists and scientific organizations to play important roles in policy making “as advocates of support, purveyors of advice, and in struggles over many policy goals” (Lakoff 2001). Especially concerning the regulation of risks and uncertainties, science found an eminent position as Funtowicz and Ravetz (1990) noted: “science was previously understood as achieving even greater certainty in our knowledge and control of the natural world; now it is seen as coping with increasing uncertainties” (p 7).

Intriguingly, Abraham (1993) described the initiation of using science in coping with risks and uncertainties:

“Risk assessment developed initially as a 'scientistic' response by industry, especially the nuclear industry, to the perceptions of environmentalist and consumer movements in the 1960s that many industrial technologies posed undesirable and unacceptable risks to (certain sections of) Society. In a similar vein, the strategy adopted by government was to rely on scientists to define risks, as a way of providing a rational basis for technology policy decisions which entailed some perceived societal hazards” (p. 387).

Van Zwanenberg and Millstone (2005) called this approach to regulation as ‘inverted decisionist’ model which is depicted in figure 1. The basic assumption of this model is

that science, in the initial phase, is capable of identifying the risks and uncertainties of new technologies far from any social, or external, forces as well as any internal biases. Therefore, it will provide a sound basis for policy makers to decide based upon that information, to accept or reject the risks and uncertainties.

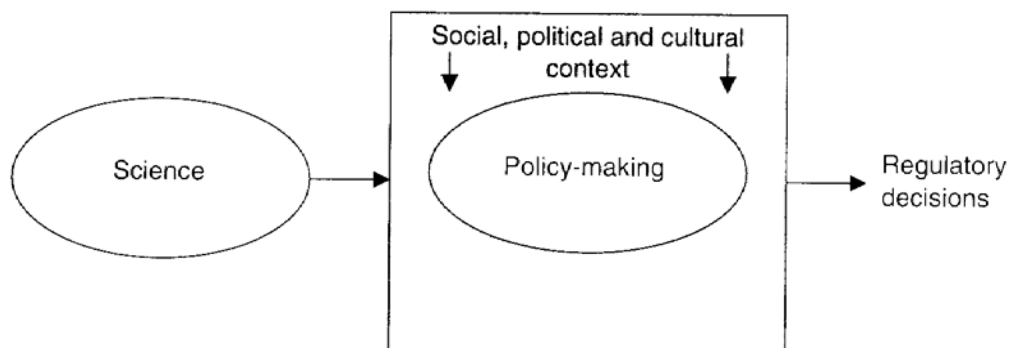


Figure 1. The inverted decisionism model (Van Zwanenberg and Millstone 2005, p. 20)

The ‘revised inverted decisionist’ model or what has been called also the ‘red book’ model³, is another suggestion based on different terminologies and consists of two stages processes: ‘risk assessment’ and ‘risk management’. According to this model, it is necessary to separate the risk assessment phase carrying out by science and scientific expertise from risk management stage which is in the context of socio-political factors. As figure 2 shows, the model assumes that risk assessment is not affecting by those contextual factors, or to say, scientific arguments are not exposed to the influence of external sources.

The ‘revised inverted decisionist’ model supposes the scientific risk assessment as the pure source of identifying the risk and uncertainties arising from new technologies and products. The core assumption of this model is that risk assessment is based on mere science and scientific considerations apart from social, political and cultural context. But it consider a place for policy makers in that contexts to decide about the result of risk assessment in the regulatory process such as selecting the identified risks as acceptable or unacceptable. This model largely implemented and used in the U.S. in the final decades of the 20th century.

³ Based on the report published by National Research Council in 1983: risk assessment in the Federal Government: managing the process

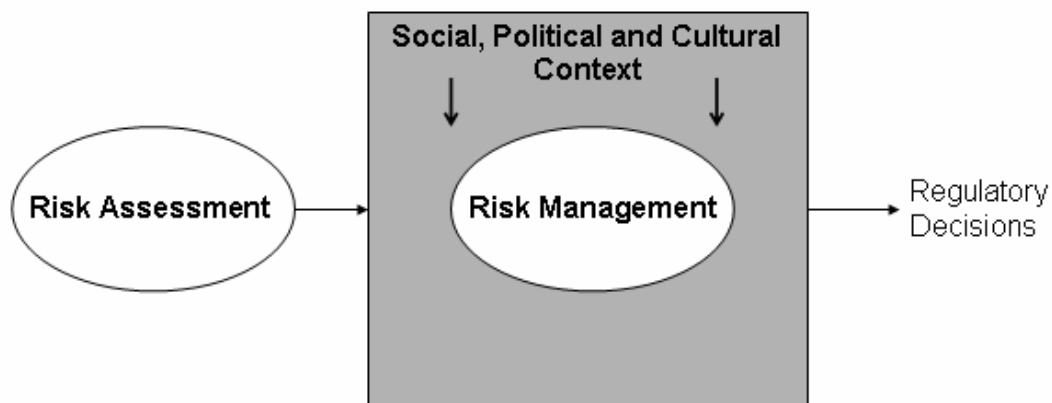


Figure 2. Revised inverted decisionist model (Van Zwanenberg and Millstone 2005 p.15)

However, a vast corpus of studies mostly based on a social constructivist views, joint by realizing the real outputs of using science in policy making led to fundamental suspicions on some assumptions of this model, chief among them the separation of science from its external socio-political contexts. The seminal paper of Weinberg (1972) pointed out the ‘trans-scientific’ matters; “questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science” (p. 209).

Different persons based on various assumptions questioned the role of science in policy making as the mere source of assessing the risks. Jasanoff (1990) did a review of the literatures on science and policy which showed different problematic aspects of using science in political contexts. They argued that while it is supposed science can provide the realistic information for the decision of policy makers; their real case studies did not confirm this position. In many instances, the outputs of scientific works are impregnated with other socio-political cultures which are not seen in those models.

Funtowicz and Calenbuhr (1999) in their prologue on Andy Stirling’s (1999) synthetic report about precautionary approach of the E.U. described the evolution of policy making processes concerning to use of science:

"The use of sophisticated scientific methods in the assessment and then management of risks began with the problems of major industrial hazards, notably those of nuclear power. At first it was believed that quantitative techniques, either of statistics or of modeling, would suffice for the guidance of risk policy and risk management. But as experience accumulated, it became clear that while science is an essential core of the assessment process, it could not be the whole."

In this environment, some scholars based on social constructivist view argued that all of those cases are signs confirming the strength of their view that science is a social construct far from realizing the truth, or even providing reliable knowledge (Van Zwanenberg and Millstone 2000). Jasanoff (1986) in seeking for an explanation of why countries made distinct regulations concerning the risk of chemical products for human health and possible cancer; attributed it to the different ways their risk assessment and

management are constructed. She also (1995) traced the source of disparities among U.S, U.K and Germany in biotech regulation in their socio-cultural traditions.

On the contrary, some scholars based on realist constructivist views attributed the problem to some framing assumptions behind scientific inquiries, or risk assessments, rather than problems in nature of science as a social construct. In a model which is called co-evolutionary model, Van Zwanenberg and Millstone (2005) put the science in the socio-political context which impose some framing assumptions about risks of technologies and might be the major source of differences between countries (Millstone et al 2004). As figure 3 shows, this does not mean that science would or could not have any useful input for policy making decisions; though it is based on non-scientific framing assumptions. For instance, governments can frame the scope of research by changing the range of phenomena that scientists must include in their research (for instance, the scope of risk must be confined just to environment or encompass both environment and human's health?); or deciding about which kinds of disciplinary specialties to be used in the assessments, the kind of evidences to be accepted as direct or indirect and so on.

More on framing

The concept of framing assumptions is a central theme in analysis of risk assessment in regulatory policy making. The concept refers to the various ways and possibilities that non scientific factors would affect scientific dealings with assessing risks and uncertainties. Both Van Zwanenberg & Millstone (2005) and Jasanoff (2005) noted that the concept of framing assumption is the result of Erving Goffman (1974) sociological works to “characterize the implicit underlying features of the world view of individuals or social groups” (Van Zwanenberg and Millstone 2005 p. 29) which “fundamentally alter people’s perceptions of what is real in the world around them” (Jasanoff 2005 p. 24).

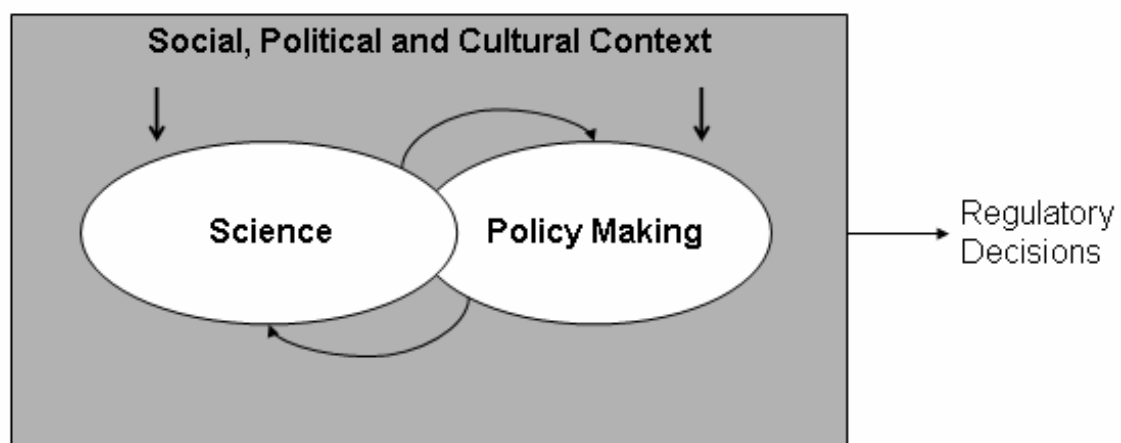


Figure 3. The realistic co-evolutionary model (from Van Zwanenberg and Millstone 2005, p. 29)

In the realist constructivist perspectives, framing which refers largely to what may be called the ‘meta-level’ of food safety governance (Dreyer et al 2008), describes the

process within which governments define the questions to be asked and the issues to be taken into account by scientific advisors and regulators (Ely 2006). According to this approach, framing assumption refers to both underlying beliefs about the world and a broader set of conditions that influence the production of scientific claims and results (Van Zwanenberg and Millstone 2005).

In some studies, realistic scholars have suggested that sources of disputes and disagreements between countries in some cases was neither the differences between their scientific conjectures nor the erosion of public trust in policy makers; but the differences in their up-stream framing assumptions. For instance, Millstone et al (2004) have found the sources of trade disputes between U.S and E.U in their contrasted framing assumptions or Millstone et al (2008) argued differences between U.S., U.K, Germany, Japan and Argentina are attributable to their various framing assumptions.

Millstone et al (2004) added the importance of framing assumptions as the ‘risk assessment policy’ stage in the model called it ‘transparent model’. As figure 4 shows, risk assessment policy is affected by socio-economic and political considerations which in turn provide inputs for the risk assessment stage which needs also scientific considerations. This model is the revised version of the ‘red book’ model including the framing assumptions. They divided the framing assumptions into ‘upstream’ and ‘downstream’ ones in which upstream framing assumptions are those before the risk assessment stage as socio-economic and political considerations; while the downstream ones are after risk assessment step, as the technical, economic and social considerations affecting risk evaluation and management.

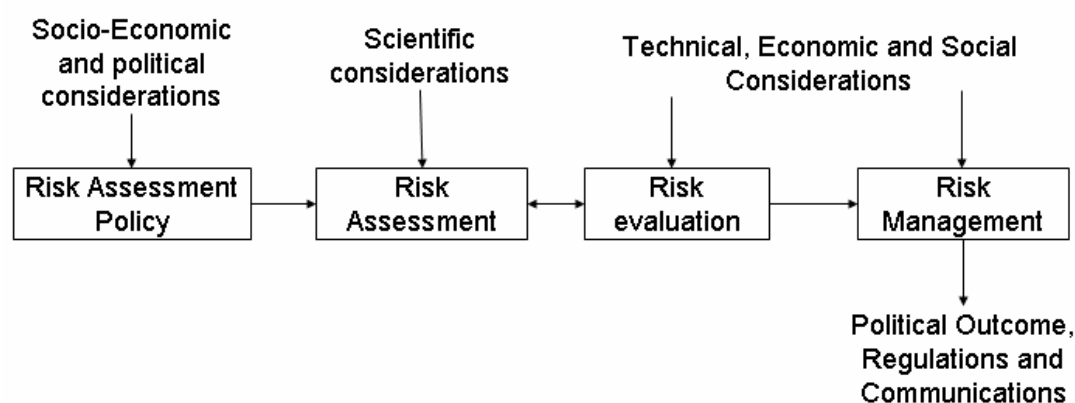


Figure 4. The transparent model of regulation (Millstone et al 2004)

Conceptually, one clear difference between these models and those developed and suggested in the innovation studies is that the former put the emphasis on the risks of technologies; while the latter pointing to the critical importance of benefits as the major mean of economic growth and welfare. Needless to say, both of them are composed of descriptive as well as prescriptive elements. Consequently, it seems that there are some limitations in each approach to can capture both risks and benefits of new technologies providing an analytical and explanatory policy tool as well as a guideline for policy makers.

In the remaining part of this paper, I shall try to firstly introduce the case of GM foods regulation in the context of the E.U. in comparison with the U.S., which the former is in opposite of the central assumptions in the innovation studies, while the latter is closer. The trend of changing legislations in both jurisdictions, however, seems in opposite of what is emphasized in innovation studies. Then, I shall discuss some potential in the co-evolutionary model which can be used for developing an analytic tool for policy makers consists of both risks and benefits of technologies, or innovations in the next section.

GM Foods regulation in the context of the U.S. and E.U.

From the mid-1980's, the approach of U.S in regulating GM products was based on risk assessments (Jasanoff 2000) based on the red book model. They were assuming GM organisms are not so novel to need *new regulations*; whereas *products* must be considered as the unit of risk assessment than processes. It is not possible to judge equally about GM products in which each of them needs to be analyzed in a *case by case* basis (OSTP 1986). In most of their case studies, regulators concluded that the risk of GM crops are not so different from their non GM counterparts and therefore there is no need for special restrictions on them (Jasanoff 1995).

As a result, until the moment a product wants to be introduced into the market, there is no need for any kinds of approval from legislative systems (ibid). Firms are able to do laboratory test and research freely before commercialization stage, even they can release the GM products at the farm level for experimental purposes. Moreover, risk appraisals mainly considered the adverse effects of environmental changes on the farmer's lands commercial prospects, not the non-agricultural environment (House of Lords 2000).

On the other side of Atlantic, Europe emerged as a different policy regime. The core regulatory principle of Europe is choosing precautionary approach⁴ presumes that GM products are inherently different from non-GM products (Levidow and Murphy 2002). The term precautionary emphasizes on the scientific unknowns about the effects of GMO products (Levidow et al 2000). In the 1990, European Commission published the council directive on the deliberate release into the environment of genetically modified organisms (GMO), to provide a set of provisions concerning these products (it is called deliberate release directive 90/220). According to this directive, each national authority has to take into account appropriate measures to avoid some adverse effects or realizing GMOs.

Contrary to the U.S, which obliged legislative approval just before market introduction of GM crops, in the European framework it is necessary to take approval also for releasing the seeds into farm level, even for experimental objectives. Moreover, consumer's risk are not deemed a problem in the U.S in which risk assessments are

⁴ Various studies and papers are about what is the precautionary approach (e.g. Harremoes et al. 2002 described the instances of using precautionary approaches in the 20th century, though not such explicit; or Stirling 1999 discussions to show what is precautionary approach and why it is not in opposite of innovation promotion). In short, this view suggests that in the situation of risk in which we have not firm scientific basis for decision making, precaution and stage by stage learning is mandatory.

concerned with environmental problems (such as biodiversity and so on); while in the E.U. risk issues are concerned as a matter of policy attention for both human health and environmental issues.

Another important factor in shaping the trans-Atlantic history of disputes was the concept of substantial equivalence which initially accepted in both jurisdictions, but then rejected in Europe. Substantial equivalence refers to: “if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected” (OECD 1993). In the U.S., firms voluntarily submitted their safety claims, including the chemical composition of GM food to show that they are substantially equivalent to their non GM counterparts. Europe also accepted a similar notion in its Novel Food Regulation 258/97 (another regulation in 1997) accepting the concept of substantial equivalence in which firms just required a scientific justification of their claim rather than doing real risk assessments in the farm level (Levidow and Morphy 2002).

Generation and application of this concept provided new opportunity for unifying the views in both the U.S. and Europe allowing free trades in a wide range of products and services (ibid). The hope of dissolving differences through using this unified approach faced sever challenges when the U.S. exports of GM soya in 1997 provoked a widespread reaction against retailing and processing of these products (Levidow and Carr 2000). In response to these disputes, the Genetic Engineering Alliances asked a ‘five year freeze’ on all commercial use or patenting these products (GEA 1999) in the European context.

The concept of substantial equivalence was also criticized by different scholars, chief among them the critical view of Millstone et al (1999) in the journal of ‘Nature’. Such criticism in turn caused a quick reply by OECD in the next issue of ‘Nature’. Debates continued until downgrading the concept by E.U in 2001 in its document, the EU stated that “this proposal does not include a notification procedure ... which are substantially equivalent to existing foods” (CEC 2001). On the other side, U.S had more tentative changes than E.U, though it abandoned the view that GM products do not present unique safety concerns (Levidow and Murphy 2002).

That old European directive 90/220 was replaced by 2001/18, which widened the scope of required risk assessments to extend from direct and short-term effects, also to include long-term and indirect ones. This shows that the E.U. is going to extend the scopes of its precaution in an era in which the innovation bottle is intensified among firms. As a result, while the U.S. market is consuming GM products in a large amount and therefore providing a worth opportunity for the firm’s innovations; the market of the E.U. is not in favor of those products, deterring and discouraging the GM foods innovations.

Hence, what is important for the E.U. is the safety and security of GMOs than the importance of innovation as the central means of economic growth and technological progress. The European people did, and are not agree, to consume the products which their consequences are unknown and might pose problems for both human’s health and

environmental diversity. Intriguingly, on the other side of Atlantic, the human's health is not deemed an area that needs even investigation.

The precautionary approach of the E.U, can therefore best be understood from the perspective of a co-evolutionary model in a dynamic process of interaction between science, policy makers and society in a larger socio-political-cultural context. In the opposite side, while the U.S. pretend to analyze the risks of new technologies; its red book model paves the way for easy legislations in favor of the firm's demands in removing the barriers of market entry.

In other words, one immediate result of considering framing assumptions in the policy making would be increasing the complexity of the process in opposite of the 'red book' simple suggestion. The red book model presupposes that science is sufficient for risk assessments far from social contexts which paves the way for easy and fast legislations in favor of firm's innovations; while this not the case in the transparent model. In the next section, I shall provide a theoretical discussion on those frameworks, their limitations and a possible approach that can help in providing a more comprehensive analytical tool in regulation of technologies.

Highlighting the policy gap and a suggestion

The importance of framing assumptions is going to become clear for policy makers in the European Countries because some reports (Millstone et al 2004, 2008) are emphasizing on the importance of explicitizing those assumptions for preventing further struggles and disputes among legislators. The case of the E.U. shows that even in the advanced countries which Pavitt (1998) recommended them to consider innovation as their high policy priority; there are some cases such as GM foods regulations that does not meet this assumption.

This might be attributed to the fact that these two different strands of studies are developed in separation, each of them highlighting a different dimension of the technological regulation. On the one hand, the important question of innovation studies concerning regulation is how is it possible to find regulatory ways which pose fewer barriers on innovations. On the other hand, the literature of risk and governance faced an increasing problem of how is it possible to regulate technologies in a way that can cope with risks and uncertainties embedded in those technologies.

Probing from another point of view, it seems that there are serious limitations in the innovation studies to illustrate the policy making systems because their theoretical insights are developed around firm's activities as the core player of the innovation systems (e.g. Edquist 2005); though they emphasized on considering the role of all actors in the innovation systems, particularly the policy making section. On the other hand, the literature of risk and governance for its increasing focus on the governance system including the public, did not pay enough attention to the firms as the basic place of occurring innovations and further benefits to the society.

The innovation studies are faced with a critical problem of considering the risks and uncertainties of new technologies, or innovations, for society. They are mostly based on a technocratic assumption that expertise body of governments can deal with regulations far from the arguments and needs of the lay public and therefore they did not consider the democratization process of regulation as a crucial factor.

The models developed for regulation of risks and uncertainties, on the other hand, mostly focused on how is it possible to handle those problems in the modern societies which are called the risk societies (Beck 1992). As a result, in their descriptions and prescriptions, the place of considering the benefits of technologies is almost empty. Although there are some studies such as Stirling (1999) who argued that the precautionary approach of the Europe is not a limit for innovations; it can not provide an analytical tool for integrating both aspects of regulation, i.e. risks and benefits.

Based on the above discussions, I would argue that there are some potentials in the co-evolutionary model as a general framework, or the transparent model as a more specified one, which can shed some lights on the possible ways in developing richer conceptual frameworks as well as the more realistic models that can be used for guiding political decisions and actions. But it needs some improvements based on the capabilities of the innovations studies which have more to do with the benefits than risks of technologies.

The initial theoretical suggestion of this paper would be replacing the term 'risk' in those models with 'risks and benefits' of technologies and innovations. This recommendation presupposes that not just arguments and assessments of risks are based on some upstream and downstream framing assumptions; but also the propositions in favor of technological benefits are framed in a socio-economic context of considerations.

Therefore, while both arguments of benefits and risks co-exist in political struggles, this new model suggests that both of them are based upon some framing assumptions and each policy analysis needs to dig up those assumptions in a comparative manner. Contrasting the framing assumptions behind both risks and benefits would be very helpful for both policy analysis and decisions. On the one hand, it will help to realize how various parties frame their arguments differently and on the other hand, it will help the decision makers making sense of how much those framing assumptions are plausible in comparison to each other. Considering the framing assumptions of risks and benefits together, I argue, will lead to sounder and more fruitful political decisions.

As a guideline, after explicitizing the assumptions, policy makers can contrast the scope of those framing assumptions and tune them up. The decision about risks and benefits of technologies needs to be taken based on equal framing assumptions as a general rule. Policy makers can identify an interesting and plausible framework of framing assumptions and ask the opponents and proponents to frame their arguments similarly.

For instance, one can argue that benefits of GM foods are just economic and physical and it has just some direct usefulness; but another one claims the risks of GMOs are not confined to physical health, but also include social and political risks for family farms and

developing countries (Jasanoff 1995) as well as many indirect effects for flora and fauna. Paying no attention to the differences of framing assumptions, at the first instance it seems that the risks of those products is more than their benefits; but after considering the differences of framing assumptions, it would be clear that those arguments are not comparable simply and it needs a similar framing assumption.

Concluding remarks:

However, empirical studies need framework for framing assumptions. Some suggestions based on Millstone (2006) distinguished between definitional, procedural and interpretative framing assumptions, though admitting that they are “interdependent:

- **Substantive** risk assessment policy issues are concerned with delineating which potential changes and effects are included within the scope of risk assessments and which are outside their scope, and which kinds of evidence are admissible and which are not.
- **Procedural** risk assessment policies are concerned with the processes by which risk assessments are conducted.
- **Interpretive** risk assessment policy issues are concerned with the ways in which data are interpreted. Data and documents do not interpret themselves; interpretation often involves judgments and assumptions” (p. 9).

This framework needs to be enhanced through more empirical studies and field works as well as conceptual works. Nevertheless, it seems it may provide a good basis for proceeding the research on this theme. Personally, I have selected this distinction and classified each item based on other studies as the framework for my research on framing assumptions of Iranian policy making system about GM foods. Data gathering in the first round will both enhance the suggested framework as well as identify the framing assumptions in the system, and the possible contrasts in the framings.

Conclusion:

Although there are vast literature and studies concerning the innovation and regulation; it seems they are based on one central assumption that in some cases is not true: taking for granted the importance of innovation as a supreme way of progress and finding the ways in which regulations pose minimum barriers in this way. The case of GM foods regulation in the E.U. is an example in which policy makers and the lay public did not agree with the innovations in the GM crops and asked a precautionary approach in those legislative systems. What is important in this case is coping with risks and uncertainties of those products rather than their benefits. However, it does not mean that this is the just counterexample; it is possible to mention other cases too. Consequently, the approaches and models of innovation studies face with serious limitation in analyzing the regulation of those innovations and there is a need for richer conceptual frameworks and policy models. What is suggested here after discussing the characteristics of two streams of research, means regulation of risks and innovation, is some potentialities in the realistic co-evolutionary model of governing risks to can involve also the benefits based

on a unified framework of framing assumptions. Nevertheless, this is the first step in unifying the models and works of two separate strands and needs much more to can yield a comprehensive and reliable framework.

References:

- Abraham J. (1993). "scientific standards and institutional interests: carcinogenic risk assessment of benoxaprofen in the UK and US." social studies of science **23**: 387-444.
- Abramovitz (1956). "Resource and output trends in the United States since 1870." American Economic Review **46**: 5-13.
- Allen T. J. Uttebrack J. M. Sirbu M. A. Ashford N. A. and Hollomon J. H. (1978). "government influence on the process of innovation in Europe and Japan." research policy **7**: 124-149.
- Arrow K. (1962). economic welfare and the allocation of resources for invention. the rate and direction of inventive activity. Princeton, Princeton university press.
- Beck U. (1992). risk society: towards a new modernity. London, Sage.
- Borrás S. and Lundvall B (1997). The Globalizing Learning Economy: Implications For Innovation Policy. Eur 18307 En Tser, Science Research and Development Luxembourg.
- Bourreau M. and Dogan P. (2001). "regulation and innovation in the telecommunications industry." telecommunications policy **25**: 167-184.
- Bowden G. (1995). coming of age in STS: some methodological musings. handbook of science and technology studies. Jasanoff S. Markle G. E. Petersen J. C. and Pinch T. London, Sage Publications.
- Buhrlen B. Blind K. and Menrad K. (2003). the impacts of regulation on th developments of new products in the pharmaceutical sector. Karlsruhe, Fraunhofer.
- Bush V. (1945). science: the endless frontier, National Science Foundation.
- CEC (2001). Proposal for a regulation on genetically modified food and feed, Commission of the European Communities.
- Dosi G. (1982). "Technological paradigms and technological trajectories: the determinants and directions of technological change and the transformation of the economy." Research Policy **11**: 147-162.
- Dosi G. (1988). the nature of the innovation process. technical change and economic theory. London and New York, Pinter Publishers.
- Dreyer M. Renn O. Ely A. Stirling A. Vos E. and Wendler F. (2008). A General Framework for the Precautionary and Inclusive Governance of Food Safety: Accounting for risks, uncertainties and ambiguities in the assessment and management of food safety threats, Safe Foods.
- Edquist C. (2001). innovation policy - a systemic approach. the globalizing learning economy. Archibugi D. and Lundvall B-A. New York, Oxford University Press.
- Edquist C. (2005). systems of innovation: perspectives and challenges. The Oxford handbook of innovation. Fagerberg J. Mowery D. and Nelson R. R. Oxford, Oxford University Press.
- Ely A. (2006). regulatory appraisals of BT maize: a study of science in governance SPRU. Brighton, Sussex. **D.Phil.**

- Ettlie J. E. (1983). "policy implications of the innovation process in the U.S food sector." research policy **12**: 239-267.
- Fagerberg J. (2005). innovation: a guide to the literature. the oxford handbook of innovation. Fagerberg J. Mowery D. and Nelson R. Oxford, Oxford University Press.
- Freeman C. (1987). technology policy and economic performance. London, Pinter.
- Funtowicz SO and Ravetz JR (1990). Uncertainty and Quality in Science for Policy Dordrecht, Kluwer academic publishers.
- GEA (1999). Five year freeze on genetic engineering and patenting in food and farming, Genetic Engineering Alliance.
- Goffman E. (1974). Frame analysis: an essay on the organization of experience. Cambridge, Harvard University Press.
- Harremoes P. Gee D. MacGarvin M. Stirling A. Keys J. Wynne B and Guedes Vaz S., Ed. (2001). late lessons from early warnings: the precautionary principle 1896-2000. Copenhagen, European Environmental Agency (EEA).
- House of Lords (2000). science and society. london, science and technology committee.
- Hughes T. P. (1987). the evolution of large technological systems. the social construction of technological systems: new directions in the sociology and history of technology. Bijker W. E. Hughes T. P. and Pinch T.J. Cambridge and London, MIT press.
- Jasanoff S. (1986). Risk management and political culture, Russel Sage Foundation.
- Jasanoff S. (1990). the fifth branch science advisors as policy makers. London, Harvard University Press.
- Jasanoff S. (1995). product, process or programme: three cultures and the regulation of biotechnology. resistance to new technology. Bauer M. Cambridge UK, Cambridge University Press: 311-331.
- Jasanoff S. (2000). "Between risk and precaution - reassessing the future of GM crops." journal of risk research **3**(3): 277-282.
- Jasanoff S. (2005). Design on Nature: Science and Democracy in Europe and the United States. Princeton and Oxford, Princeton University Press.
- Lakoff S. A. (2001). politics and the communities of science. science technology and governance. de la Mothe J. London and New York, continuum.
- Lanjouw J. O. and Mody A. (1996). "innovation and the international diffusion of environmentally responsive technology." research policy **25**: 549-571.
- Levidow L. and Carr S. (2000). "UK: precautionary commercialization?" journal of risk research **3**(3): 261-270.
- Levidow L. and Murphy J. (2002). the decline of substantial equivalence: how civil society demoted a risky concept. Science and citizenship in a global context: challenges from new technologies. Institute of Development Studies University of Sussex.

- Levidow L. Carr S. and Wield D. (2000). "Genetically modified crops in the European Union: regulatory conflicts as precautionary opportunities." Journal of Risk Research **3**(3): 189-208.
- Lundvall B-A. (1988). innovation as an interactive process: from user-producer interaction to the national systems of innovation. technical change and economic theory. Dosi G. et al. London and New York,, Pinter publishers.
- Lundvall B-A., Ed. (1992). national systems of innovation: towards a theory of innovation and interactive learning. London, Pinter publishers.
- Martin B. and Nightingale P, Ed. (2000). the political economy of science, technology and innovation, Elgar.
- Metcalfe S.J. (1994). "evolutionary economics and technology policy." The Economic Journal **104**(425): 931-944.
- Metcalfe S.J. (1995). the economic foundations of technology policy: equilibrium and evolutionary perspectives. handbook of the economics of innovation and technical change. Stonman P. oxford, blackwell.
- Millstone E. (2006). Science, risk and governance: radical rhetorics and the realities of reform. SPRU's 40th anniversary. SPRU Brighton.
- Millstone E. Brunner E and Mayer S. (1999). "beyond substantial equivalence." nature **401**: 525-526.
- Millstone E. Van Zwanenberg P. Levidow L. Spok A. Hirakawa H. and Matsuo M. (2008). risk-assessment policies: differences across jurisdictions. Seville, institute for prospective technological studies (ipts).
- Millstone E. Van Zwanenberg P. Marris C. Levidow L. and Torgersen H. (2004). science in trade disputes related to potential risks: comparative case studies. Seville.
- Montalvo C. (2007). "explaining and predicting the impact of regulation on innovation: towards a dynamic model." international journal of public policy **2**: 5-31.
- Mowery D. (1995). the practice of technology policy. handbook of the economics of innovation and technical change. S. P. Oxford, Blackwell: 513-557.
- Nelson R.R. (1959). "the simple economics of basic scientific research." journal of political economy **67**(3): 297-306.
- Nelson R.R. and Winter S. (1977). "in search of useful theory of innovation." Research Policy **6**: 36-76.
- Nelson R.R. and Winter S. (1982). an evolutionary theory of economic change. Cambridge MA, Belknap press, Harvard University.
- Nelson R.R., Ed. (1993). national innovation systems: a comparative analysis. Oxford, Oxford university press.
- NRC, U. (1983). risk assessment in the federal government: managing the process. Washington DC, US national academic press.
- OECD (1993). Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles. Paris, Organisation for Economic Cooperation and Development.
- OSTP (1986). coordinated framework for regulating biotechnology, office of science and technology.

- Patel P. and Pavitt K. (1987). "is western Europe losing the technological race?" research policy **16**: 59-85.
- Rosenberg N. (1963). "technical change in the machine tool industry." journal of economic history **23**: 414-443.
- Rosenberg N. (1982). inside the black box: technology and economics. Cambridge, Cambridge university press.
- Rothwell R. (1992). "industrial innovation and government environmental regulation: some lessons from the past." technovation **12**(7): 447-458.
- Schnee J. E. (1979). "R&D strategy in the U.S pharmaceutical industry." research policy **8**: 364-382.
- Smith K. (1991). innovation policy in an evolutionary context. evolutionary theories of economic and technical change. Saviotti P. and Metcalfe S. London, Harwood.
- Solow R. (1956). "a contribution to the theory of economic growth." the review of economics and statistics **39**(3): 312-320.
- Solow R. (1957). "technical change and the aggregate production function." review of economics and statistics **39**: 312-320.
- Stirling A. (1999). on science and precaution in the management of technological risk, institute for prospective technological studies (ipts). **1**.
- Thomas L. G. (1994). "implicit industrial policy: the triumph of Britain and the failure of France in global pharmaceuticals." industrial and corporate change **3**(2): 451-489.
- Van Zwanenberg P. and Millstone E. (2000). "beyond skeptical relativism: evaluating the social constructions of expert risk assessments." science, technology and human values **25**(3): 259-282.
- Van Zwanenberg P. and Millstone E. (2005). BSE: risk, science and governance. New York, Oxford University Press.
- Weinberg A. (1972). "science and trans-science." minerva **10**: 209-222.